

Amendments to the Claims:

The following is a complete list of claims indicating the changes incorporated by the present amendment and replacing all prior versions of the claims. Any claims canceled herein and all deletions made in claims that are not canceled herein are done so without prejudice to being re-instituted at a later date in this or a related application.

Claim 1 (currently amended): A method for the manufacture of a pharmaceutical tablet which upon oral ingestion delivers a first drug by immediate release and a second drug by prolonged release defined as a release rate into gastrointestinal fluid that is slow enough to leave at least about 40% of said second drug unreleased one hour after ingestion, said method comprising:

- (a) dispersing said second drug in a solid matrix to form a unitary body which upon immersion in gastrointestinal fluid releases said second drug by prolonged release;
- (b) depositing on a surface of said unitary body a polymeric film that is devoid of either said first drug or said second drug and is soluble in gastrointestinal fluid;
- (c) depositing over said polymeric film a fluid medium comprising said first drug and a liquid carrier that does not remove said polymeric film upon contact therewith; and
- (d) evaporating said liquid carrier from said fluid medium thus deposited to leave a solid layer containing said first drug over said unitary body.

Claim 2 (original): The method of claim 1 in which said solid matrix is a member selected from the group consisting of celluloses, substituted celluloses, microcrystalline cellulose, polysaccharides, substituted polysaccharides, poly(alkylene oxide)s, poly(vinyl alcohol), starch, starch-based polymers, crosslinked poly(acrylic acid)s, and substituted crosslinked poly(acrylic acid)s.

Claim 3 (original): The method of claim 1 in which said solid matrix is a member selected from the group consisting of poly(ethylene oxide), hydroxypropyl methyl cellulose, and combinations of poly(ethylene oxide) and hydroxypropyl methyl cellulose.

Claim 4 (original): The method of claim 1 in which said polymeric film is a member selected from the group consisting of poly(ethylene oxide), hydroxypropyl methyl cellulose, polyvinyl alcohol, combinations of poly(ethylene oxide) and hydroxypropyl methyl cellulose, and combinations of polyvinyl alcohol and poly(ethylene oxide).

Claim 5 (original): The method of claim 1 in which said fluid medium comprises a liquid solution of said first drug in a solvent.

Claim 6 (original): The method of claim 1 in which said fluid medium comprises a liquid solution of said first drug and a polymer in a solvent.

Claim 7 (original): The method of claim 1 in which said fluid medium comprises a suspension of said first drug in solid particle form in a liquid suspending agent.

Claim 8 (original): The method of claim 1 in which said fluid medium comprises a suspension of said first drug in solid particle form and a dispersing agent, also in solid particle form, in a liquid suspending agent, said dispersing agent being a substance that separates into discrete particles upon contact with gastrointestinal fluid.

Claim 9 (original): The method of claim 1 in which said fluid medium is an aqueous suspension of said first drug, and said first drug is comprised of particles having a weight-averaged diameter equal to or less than 25 microns.

Claim 10 (original): The method of claim 1 in which said fluid medium is an aqueous suspension of said first drug, and said first drug is comprised of particles having a weight-averaged diameter equal to or less than 10 microns.

Claim 11 (original): The method of claim 1 in which the weight ratio of said polymeric film to said unitary body is from about 0.005:1 to about 0.2:1.

Claim 12 (original): The method of claim 1 in which the weight ratio of said polymeric film to said unitary body is from about 0.01:1 to about 0.1:1.

Claim 13 (original): The method of claim 1 in which the weight ratio of said polymeric film to said unitary body is from about 0.01:1 to about 0.08:1.

Claim 14 (original): The method of claim 1 in which (b) comprises surrounding said unitary body entirely with said polymeric film, and said solid layer of (d) is a shell completely encasing said unitary body and polymeric film.

Claim 15 (original): The method of claim 1 in which (b) and (c) comprise depositing said polymeric film and said first drug over only a portion of the entire surface of said unitary body, leaving the remainder of said unitary body exposed.

Claim 16 (original): The method of claim 1 in which said liquid carrier of step (c) is water.

Claim 17 (original): The method of claim 1 in which said liquid carrier of step (c) is an organic solvent.

Claim 18 (original): The method of claim 17 in which said organic solvent is a member selected from the group consisting of ethanol, hexanes, chloroform, carbon tetrachloride, and dimethyl sulfoxide.

Claim 19 (currently amended): A dosage form for delivering a first drug that is immediately releasable upon ingestion and a second drug that is releasable by prolonged release defined as a release rate that is slow enough to leave at least about 40% of said second drug unreleased one hour after ingestion, said dosage form comprising:

a prolonged-release section comprising said second drug dispersed in a solid matrix that releases said second drug by prolonged release upon immersion of said dosage form in gastrointestinal fluid;

a polymeric film adhering to a surface of said prolonged-release section, said polymeric film being soluble in penetrable by gastrointestinal fluid and devoid of both said first drug and said second drug; and

an immediate-release section comprising a solid layer adhering to said polymeric film, said solid layer comprising said first drug dispersed in a matrix that promotes immediate release of said first drug upon immersion of said dosage form in gastrointestinal fluid.

Claim 20 (original): The dosage form of claim 19 in which said solid matrix is a member selected from the group consisting of celluloses, substituted celluloses, microcrystalline cellulose, polysaccharides, substituted polysaccharides, poly(alkylene oxide)s, poly(vinyl alcohol), starch, starch-based polymers, crosslinked poly(acrylic acid)s, and substituted crosslinked poly(acrylic acid)s.

Claim 21 (original): The dosage form of claim 19 in which said solid matrix is a member selected from the group consisting of poly(ethylene oxide), hydroxypropyl methyl cellulose, and combinations of poly(ethylene oxide) and hydroxypropyl methyl cellulose.

Claim 22 (original): The dosage form of claim 19 in which said polymeric film is a member selected from the group consisting of poly(ethylene oxide), hydroxypropyl methyl cellulose, polyvinyl alcohol, combinations of poly(ethylene oxide) and hydroxypropyl methyl cellulose, and combinations of polyvinyl alcohol and poly(ethylene oxide).

Claim 23 (original): The dosage form of claim 19 in which said solid matrix of said unitary body is defined as a first solid matrix and said fluid medium comprises said first drug in particle form and a second solid matrix, also in particle form, said second solid matrix being a substance that separates into discrete particles upon immersion in gastrointestinal fluid.

Claim 24 (original): The dosage form of claim 19 in which the weight ratio of said polymeric film to said unitary body is from about 0.005:1 to about 0.2:1.

Claim 25 (original): The dosage form of claim 19 in which the weight ratio of said polymeric film to said unitary body is from about 0.01:1 to about 0.1:1.

Claim 26 (original): The dosage form of claim 19 in which the weight ratio of said polymeric film to said unitary body is from about 0.01:1 to about 0.08:1.

Claim 27 (original): The dosage form of claim 19 in which said polymeric film and said immediate-release section constitute a shell that fully encases said prolonged-release section.

Claim 28 (original): The dosage form of claim 19 in which said polymeric film and said immediate-release section cover a portion of the surface of said prolonged-release section, leaving the remainder of said prolonged-release section exposed.

Claim 29 (original): The dosage form of claim 19 in which one of said first and second drugs is a diuretic and the other is a member selected from the group consisting of angiotensin converting enzyme inhibitors and angiotensin II antagonists.

Claim 30 (original): The dosage form of claim 29 in which said diuretic is a loop diuretic.

Claim 31 (original): The dosage form of claim 30 in which said loop diuretic is a member selected from the group consisting of furosemide, torsemide, ethacrynic acid, and bumetanide.

Claim 32 (original): The dosage form of claim 29 in which said diuretic is a thiazide diuretic.

Claim 33 (original): The dosage form of claim 34 in which said thiazide diuretic is a member selected from the group consisting of chlorothiazide, bendoflumethazide, hydroflumethazide, trichlorthiazide, chlorthalidone, indapamide, metolazone, quinethazone and hydrochlorthiazide.

Claim 34 (original): The dosage form of claim 29 in which said diuretic is a potassium-sparing diuretic.

Claim 35 (original): The dosage form of claim 34 in which said potassium-sparing diuretic is a member selected from the group consisting of amiloride hydrochloride and triamterene.

Claim 36 (original): The dosage form of claim 19 in which said first drug is a member selected from the group consisting of lisinopril and losartan, and said second drug is a diuretic.

Claim 37 (original): The dosage form of claim 19 in which said first drug is a glitazone, and said second drug is metformin hydrochloride.

Claim 38 (original): The dosage form of claim 19 in which said first drug is pyridoxine hydrochloride, and said second drug is a member selected from the group consisting of atorvastatin, simvastatin, pravastatin, lovastatin, cerivastatin, rosuvastatin, and fluvastatin.

Claim 39 (original): The dosage form of claim 19 in which said first drug is pyridoxine hydrochloride, and said second drug is a member selected from the group consisting of atorvastatin and simvastatin.

Claim 40 (original): The dosage form of claim 19 in which said second drug is a member selected from the group consisting of metformin hydrochloride, vancomycin hydrochloride, captopril, erythromycin lactobionate, ranitidine hydrochloride, sertraline hydrochloride, ticlopidine hydrochloride, amoxicillin, cefuroxime axetil, cefaclor, clindamycin, doxifluridine, tramadol, fluoxetine hydrochloride, ciprofloxacin hydrochloride, gancyclovir, bupropion, lisinopril, cefaclor, saquinavir, ritonavir, nelfinavir, clarithromycin, azithromycin, ceftazidime, cyclosporin, digoxin, paclitaxel, iron salts, topiramate, and ketoconazole.

Claim 41 (original): The dosage form of claim 19 in which said second drug is a member selected from the group consisting of lisinopril, enalapril, captopril, fosinopril, quinapril, ramipril, and benazepril.

Claim 42 (original): The dosage form of claim 19 in which said second drug is a member selected from the group consisting of losartan, valsartan, candesartan, irbesartan, telmisartan, and eprosartan.

Claim 43 (original): The dosage form of claim 19 in which said first drug is a sulfonylurea selected from the group consisting of glimepiride, glyburide, and glipizide, and said second drug is metformin hydrochloride.

Claim 44 (original): The dosage form of claim 19 in which said first drug is glimepiride and said second drug is metformin hydrochloride.

Claim 45 (original): The dosage form of claim 19 in which said first drug is glyburide and said second drug is metformin hydrochloride.

Claim 46 (original): The dosage form of claim 19 in which said first drug is glipizide and said second drug is metformin hydrochloride.